

**510(k) Summary**

JUL 30 2012

Proprietary Name: Hip Systems

Common Name: Artificial Hip Replacement Components –Acetabular and Femoral

Classification Names And References: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR §888.3358

Hip joint metal/polymer constrained cemented or uncemented prosthesis. 21 CFR §888.3310

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR §888.3353

Hip joint metal/polymer semi-constrained cemented prosthesis 21 CFR §888.3350

Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR §888.3360

Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 21 CFR §888.3390

Proposed Regulatory Class: Class II

Product Codes:

- LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented
- KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer
- LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented
- MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous
- JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented
- LWJ - prosthesis, hip, semi-constrained, metal/polymer, uncemented
- KWL - prosthesis, hip, hemi-, femoral, metal
- MAY - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish
- KWY - prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented
- MBL - prosthesis, hip, semi-constrained, uncemented, metal/polymer, porous

For Information contact: Karen Ariemma, RAC  
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Mahwah, NJ 07430  
Phone: (201) 831-5718 Fax: (201) 831-4718

Date Prepared: July 29, 2012

**Description:**

The devices included in this submission are femoral stems, femoral heads, acetabular shells, acetabular inserts, modular necks, modular stems and accessory components used in hip arthroplasty procedures. All devices have been previously deemed substantially equivalent in prior 510(k) submissions and are commercially available. The purpose of this submission is to modify the labeling of these devices to include safety information in the Instructions for Use (IFUs) regarding modular hip stem junctions. In addition to this specific update, general revisions have been made to the IFUs to harmonize the language between the Howmedica Osteonics' hip stem labeling

**Intended Use:**

The hip system devices included in this submission are sterile, single-use devices intended for use in primary and revision total hip arthroplasty to alleviate pain and restore function.

**Indications:**

The overall indications for use for the subject total and hemi hip replacement prostheses include:

1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The Rejuvenate Hip System is intended for cementless use only.

*Additional indications specific to the Hipstar Stem:*

The Hipstar Femoral Stem is intended for cementless use only.

When mated with a constrained acetabular liner the Hipstar Stem is indicated for use in primary and revision total hip arthroplasty for patients at high risk of hip dislocation due to a history of prior dislocations, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

*Additional indications specific to the Restoration Modular Hip System:*

The Restoration Modular Hip System is intended for primary and revision total hip arthroplasty as well as in the presence of severe proximal bone loss. These femoral stems are designed to be press fit into the proximal femur.

**Substantial Equivalence:**

The subject hip system devices have been deemed substantially equivalent to other commercially available hip arthroplasty systems based upon an evaluation of intended use, design, materials, and operational principles in prior 510(k) submissions. The purpose of this submission is solely to revise the labeling to add safety information regarding modular hip stem taper junctions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.  
% Ms. Karen Ariemma  
Senior Strategic Regulatory Affairs Manager  
325 Corporate Drive  
Mahwah, New Jersey 07430

JUL 30 2012

Re: K121308

Trade/Device Name: Hip Systems  
Regulation Number: 21 CFR 888.3358  
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated  
uncemented prosthesis  
Regulatory Class: Class II  
Product Code: LPH, KWZ, LZO, MEH, JDI, LWJ, KWL, MAY, KKY, MBL  
Dated: April 30, 2012  
Received: May 1, 2012

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

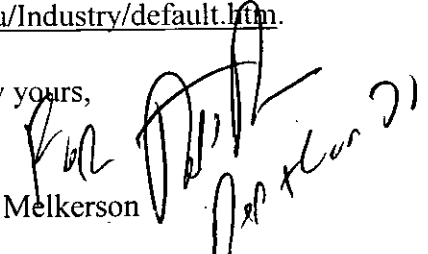
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121308 (pg 1/1)

Device Name: Stryker Hip Systems

Indications for Use:

The overall indications for use for the subject total and hemi hip replacement prostheses include:

1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The Rejuvenate Hip System is intended for cementless use only.

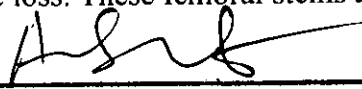
*Additional indications specific to the Hipstar Stem:*

The Hipstar Femoral Stem is intended for cementless use only.

When mated with a constrained acetabular liner the Hipstar Stem is indicated for use in primary and revision total hip arthroplasty for patients at high risk of hip dislocation due to a history of prior dislocations, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

*Additional indications specific to the Restoration Modular Hip System:*

The Restoration Modular Hip System is intended for primary and revision total hip arthroplasty as well as in the presence of severe proximal bone loss. These femoral stems are designed to be press fit into the proximal femur.

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
510(k) Number K121308  
(21 CFR 807 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)